

Dear Judge Tennyson:

Walmart requests that the Court: (1) enforce its September 25 Order compelling the government to identify the prescriptions in its Complaint, which it has not done; (2) compel the government to explain why it contends those prescriptions are invalid; and (3) include the subpoenaed federal agencies in party discovery in light of recent events. Exs. A–K.

Issue 1: The Government Must Comply with this Court’s Order to Identify Prescriptions

To establish a violation of the Controlled Substances Act (“CSA”) the government must prove two things for each prescription: (1) a prescriber wrote an invalid prescription (*i.e.*, the prescription was issued outside the usual course of professional practice) and (2) a pharmacist dispensed the prescription knowing it was invalid. 21 C.F.R. § 1306.04(a). The government sued Walmart claiming, in part, that Walmart pharmacists violated the CSA by dispensing prescriptions that had certain characteristics, so-called “Red Flags,” that “on their face could not be [for] a legitimate medical purpose under any set of circumstances.” D.I. 151 at 12:22–13:8 (Ex. L).

This Court ordered the government more than four months ago to identify, during fact discovery, the prescriptions it intends to pursue against Walmart. *Id.* at 20:10–13 (“[I]f there’s a prescription that you intend [to] use as a basis for a violation in this case, you need to provide the requested number in Interrogatory Number 1 and RFP Number 6 in fact discovery.”). The government admitted its obligation is to “identify[] now each prescription that forms the basis of each of the United States’ claims for civil penalties under 21 C.F.R. § 1306.04, as opposed to . . . waiting until expert discovery[.]” 10/25/24 U.S. Resps. at 2 (Ex. D). The government has failed to do so. Instead, on October 25, the government produced an Excel file that bore little resemblance to the government’s Complaint and that the government later admitted during a meet-and-confer was “preliminary” and not ready for “primetime.” 12/11/24 Ltr. at 2 (Ex. M). The government then revived the position previously rejected by this Court, saying it would not provide a “real” list of prescriptions until expert discovery. *Id.*

The government’s latest excuse is that, despite having been at this for eight years and having reviewed more than 6 million prescription records during its investigation, it wants to start over. It is asking this Court to allow it to do so by ordering Walmart to produce hundreds of millions of new prescriptions involving the private medical records of over 40 million Americans. The government admits that those new prescriptions have nothing to do with the prescriptions in its Complaint. Rather, the government intends to use the data improperly to scour for new “violations,” including new prescribers and new “Red Flag” prescriptions, and then ambush Walmart with those new claims during expert discovery. 1/16/25 Ltr. at 2, 5 (Ex. N); 1/07/25 Ltr. at 2, 19 (Ex. O); D.I. 150 at 1–2 (Ex. P).

The government’s efforts to expand this case are difficult to understand. It is already failing to meet its discovery obligations for the more than 80,000 prescriptions in its Complaint. *See* Prescriptions Alleged in the Second Amended Complaint (Ex. A). Despite document discovery being half over, the government is still at the starting line. The government recently withdrew half of the custodians it previously proposed. It has offered search terms for only two of Walmart’s RFPs, after failing to respond to Walmart for five months. It still has not produced the case files for five of the nine at-issue prescribers it prosecuted. And none of the nine federal agencies have

produced a single new, non-public document. At this rate, the government will not finish its productions by the Court's September 5 deadline. Walmart expects it will be forced to raise those issues shortly.

Regardless, there is no reason for the government to postpone identifying the relevant prescriptions because it is not entitled to seek discovery for claims it has not pled. The Federal Rules restrict discovery to "nonprivileged matter that is relevant to [a] party's claim . . . and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). That language limits discovery to the "actual claims"—parties cannot use discovery "to develop new claims . . . not already identified in the pleadings." Adv. Com. Note to Fed. R. Civ. P. 26(b)(1) (2000). While a plaintiff may use discovery "to adduce evidence in support of the cognizable claims set out in his complaint, he is not entitled to discovery for the purpose of determining whether or not there may be a factual basis for a claim he has not made." *In re ML-Lee Acquisition Fund II, L.P.*, 151 F.R.D. 37, 41 (D. Del. 1993); *see also U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 195 (5th Cir. 2009) (discovery must be "targeted to the claims alleged"; it is not "a search for new claims"); *Gravelle v. Avis Indus. Corp.*, 2021 WL 4204947, at *2 (7th Cir. Sept. 16, 2021) ("[D]iscovery is not an opportunity to fish for new claims."). In short, the "purpose of discovery is to find out additional facts about a well-pleaded claim, not to find out whether such a claim exists." *Stoner v. Walsh*, 772 F. Supp. 790, 800 (S.D.N.Y. 1991).

The government has never disputed this basic principle—which vitiates its primary defense to Walmart's motion. However, the government persists in its attempt to redefine its CSA "claims" at a sky-high level of generality. It characterizes its legal theories of liability as two overarching "claims," and then demotes its actual claims for civil penalties to so-called "exemplar violations." 1/07/25 Ltr. at 2, 19 (claiming the right to "seek[] statutory penalties for all violations of the claims") (Ex. O); 1/16/25 Ltr. at 5 (attacking Walmart's "position that each violation is a claim") (Ex. N). None of this wordplay succeeds.

The Third Circuit has defined a "claim" as "the aggregate of operative facts which give rise to a right enforceable in the courts." *Cristin v. Brennan*, 281 F.3d 404, 418 (3d Cir. 2002). A plaintiff thus pleads a claim by alleging facts supporting a set of elements which, if proven, entitle him to relief. 12/13/24 Ltr. at 4 (collecting authorities) (Ex. Q). And there is no dispute about what the CSA requires: The government may secure civil penalties *only* on a prescription-by-prescription basis. That is because each prescription filled in violation of 21 C.F.R. § 1306.04(a) is a distinct "[u]nlawful act[]," 21 U.S.C. § 842(a)(1), for which the government may obtain a separate civil penalty, *id.* § 842(c)(1)(A). As such, the "claims" in this suit concern the thousands of prescriptions identified in the Complaint. Had the government actually pled the claim at the level of generality for which it is now trying to seek discovery, it would never have survived a motion to dismiss. Indeed, another court addressing a similar CSA complaint held exactly that. *United States v. Ridley's Family Markets Inc.*, 20-cv-173, D.I. 74 (D. Utah June 27, 2022) (government cannot "make a blanket accusation without alleging facts that make the claim plausible and then . . . conduct an incessant fishing expedition.") (Ex. R).

The government's primary response has been to insist that Judge Connolly and this Court already resolved this dispute in its favor. 1/16/25 Ltr. at 2 (Ex. N). But Judge Connolly simply refused to strike portions of the Complaint and instead suggested it be addressed through "discovery parameters," precisely as Walmart is proposing now. D.I. 108 at 93–94 (Ex. W). And

this Court’s remark that the government may “supplement” its initial list was not (and could not have been) an endorsement of the government’s later attempt to radically expand its case beyond its pleadings. D.I. 151 at 16 (Ex. L). There is a proper way to “supplement” claims in a civil action: seek leave to amend the complaint based on evidence obtained through properly restrained fact discovery. But no party may use discovery to conduct an open-ended hunt for new claims.

Regardless, the government’s plan to ambush Walmart with new prescription claims during expert discovery would make it impossible for Walmart to seek fact discovery on the government’s claims. As Walmart previously noted, Walmart must be able “to conduct meaningful *fact discovery* into the challenged prescriptions and any potential defenses.” D.I. 149 at 2 (emphasis added) (Ex. S). The Court already ordered the government to provide its list now. The government clings to the Court’s reference to the federal rules having a mechanism for supplementing discovery responses to justify withholding its “real” list until expert discovery. This cannot be. The Court ordered the government to identify the prescriptions it seeks to pursue at trial, not provide a non-responsive placeholder.

Issue 2: Information Regarding Allegedly Invalid Prescriptions

The government refuses to adequately respond to Walmart’s Interrogatory 2, which asks the government to identify, for each prescription it contends is invalid, the bases for its allegation. *See, e.g.*, 5/31/24 U.S. Resps. at 21–22 (Ex. B); 10/22/24 U.S. Resps. at 3–4 (Ex. C); 11/21/24 U.S. Resps. at 3–7 (Ex. E).

The government has been all over the map on this simple request. First, on November 21, the government identified “the [21] categories that were applied to derive the lists of prescriptions identified in the October 25, 2024, Response.” 11/21/24 U.S. Resps. at 4–6 (Ex. E). The government did not identify any exceptions to these categories, consistent with the “Red Flag” *per se* theory of invalidity that the government advanced at the September hearing. In a letter dated January 16, however, the government acknowledged, contrary to what it told the Court, that there may be exceptions to the categories it previously identified, but that it would not identify those exceptions until expert discovery. 1/16/25 Ltr. at 4–5 (the government “may decline to seek penalties for prescription fills for high dosages of opioids where there is some indication from the data fields . . . that the customer had a cancer diagnosis that may have theoretically warranted a stronger opioid dose.”) (Ex. N). Those unidentified exceptions render the government’s prior disclosures essentially worthless; without the actual criteria for invalid prescriptions Walmart cannot conduct relevant discovery.

The government’s change in course has other discovery implications. At the September hearing, the government successfully argued against providing discovery into the prescribers who wrote the “Red Flag” prescriptions because “the particular combination of drugs, the dosage, or other characteristics that are apparent from Walmart’s dispensing data” indicate that the “prescription would simply not have a legitimate medical purpose and it really doesn’t matter who the prescriber is.” D.I. 151 at 27:19–24 (Ex. L). It is worth noting that the “Red Flags” identified by the government are contained nowhere in the CSA or its implementing regulations, and the DEA has expressly denied that there are categories of prescriptions that are *per se* invalid. *See* 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006) (Ex. X); 11/4/19 Ltr. at 1–2 (Ex. Y). Nevertheless, the government’s revised position—that there are certain exceptions to its “Red Flag” categories based

on a doctor's treatment of a patient and other yet to be disclosed factors—demonstrates that there likely *is* relevant information in its files about the prescribers who wrote these prescriptions. If the government has abandoned its position that “Red Flag” prescriptions are *per se* invalid, the Court should order the government to produce information in its possession concerning the prescribers of those prescriptions.

Regardless, the government must have had a basis for the claims it pled, including why it contends certain prescriptions are invalid. For Walmart “to conduct meaningful *fact discovery* into the challenged prescriptions and any potential defenses,” D.I. 149 at 2 (emphasis added) (Ex. S), the requested information regarding the “Red Flag” prescriptions must be disclosed *during* that discovery. Any other option would severely prejudice Walmart. *Cf. Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 273 (3d Cir. 2001) (prejudice includes “additional discovery, cost, and preparation to defend against new facts or new theories”). Nor can the government use the pretense of supplementation “to provide an extension of the deadline by which [it] must deliver the lion’s share of its [] information.” *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc.*, 73 F.3d 546, 571 (5th Cir. 1996); *see BTR Dunlop, Inc. v. Rockwell Int’l Corp.*, 1992 WL 361773, at *1 (N.D. Ill. Nov. 25, 1992) (finding supplementation based on “ongoing investigations” “regrettably unworkable”). Document discovery has been ongoing for more than nine months and over half the allotted time has elapsed. It is past time for the government to provide its prescription-by-prescription bases for which it claims invalidity.

Issue 3: Discovery from Federal Agencies

Walmart served document requests seeking discovery from Health and Human Services (“HHS”), Centers for Medicare and Medicaid Services (“CMS”), Indian Health Service (“IHS”), Veterans Affairs (“VA”), the Federal Bureau of Investigation (“FBI”), and the Department of Defense (“DoD”) (the “Agencies”) in May of 2024. Exs. F–K. Now nine months later, none of the Agencies have substantively responded or produced a single new document. As described below, the Court should order the Agencies to participate in party discovery given those Agencies’ delay tactics and new evidence concerning their involvement in the Walmart investigation.

The government first argued Walmart must serve subpoenas. D.I. 150 at 3 (Ex. P). The government claimed it was “not arguing that Walmart is not entitled to get discovery from these other agencies,” because it “still ha[s] the Rule 45 process to get documents from those agencies and [] the scope of discovery is still governed by Rule 26.” D.I. 151 at 49:25–50:4 (Ex. L). The Court excluded the Agencies from party discovery, directing that Walmart could seek “discovery through subpoenas because it sounds like they may have relevant information.” *Id.* at 56:1–3.

Walmart served subpoenas in October, but the government pulled a bait-and-switch. The Agencies either failed to timely respond, responded with boilerplate objections, or both. All of the Agencies asserted that their *Touhy* regulations applied and that they would decide whether to respond only after Walmart complied with them. Ex. T. After Walmart responded to the Agencies and noted that the *Touhy* objections were frivolous, the Federal Programs branch at DOJ intervened on behalf of the Agencies on December 6 and asked for additional time to consider Walmart’s position. A month later, Federal Programs replied, describing Walmart’s position that *Touhy* does not apply where the United States is a party as “untenable” and confirming that the Agencies would be standing on their *Touhy* objections. 1/6/25 Ltr. at 2 (Ex. U). Federal Programs then requested

a joint meet-and-confer with Walmart and trial counsel at Consumer Protection Branch (CPB), at which both DOJ components confirmed that the parties were at an impasse on the *Touhy* issue.

Walmart therefore filed its motion for a hearing. Yesterday, new lawyers at the CPB—that is, the same group at the DOJ leading this case—notified Walmart that *it* would be representing the Agencies (not Federal Programs), and that the United States would withdraw its *Touhy* objections for all but one of the Agencies.¹ Given the government’s nine-month runaround on Walmart’s basic discovery requests, it is clear that the Court’s intervention is still needed to move this case forward without further undue delay.

Waiver: The Agencies have waived their objections by failing to timely or properly respond. Fed. R. Civ. P. 45(d)(2)(B); *AMMEX Corp. v. Yudi*, 2024 WL 4392787, at *3 (D.N.J. Oct. 3, 2024); *In re Sevier*, 2022 WL 3923679, at *2 (D. Del. Aug 31, 2022). DoD, FBI, and VA all missed their deadlines to object. *See* Ex. T (Agency Responses). The rest asserted only invalid boilerplate objections “to the extent” the Subpoenas sought certain information. *Id.*; *Ceuric v. Tier One*, 325 F.R.D. 558, 561 (W.D. Pa. 2018).

***Touhy* Objections:** The Agencies cannot rely on *Touhy* regulations to constrain disclosure where “the federal government is a party.” *Alexander v. FBI*, 186 F.R.D. 66, 70 (D.D.C. 1998). “[W]hen the United States *is* a party to the litigation, the reach of disclosure-limiting *Touhy* regulations ends at the courthouse doors.” *Res. Invs., Inc. v. United States*, 93 Fed. Cl. 373, 380 (Fed. Cl. 2010). The Agencies are withdrawing their frivolous objections because the *Touhy* regulations and court decisions are clear.

- **CMS / HHS / IHS:** “This part **does not apply** to: (1) Any civil or criminal proceedings **where the United States**, the Department of Health and Human Services, and any agency thereof, or any other Federal agency **is a party**.” 45 C.F.R. § 2.1(d)(1) (emphasis added).
- **VA:** “Sections 14.800 through 14.810 **do not apply** to [l]egal proceedings in which [VA], the Secretary of Veterans Affairs **or the United States is a party**, is represented or has a direct and substantial interest.” 38 C.F.R. § 14.801(b)(2)(i) (emphasis added).
- **FBI:** “In any federal or state case or matter **in which the United States is not a party . . .**” 28 C.F.R. § 16.22(a) (emphasis added).
- **DoD:** “[F]undamental fairness dictates that the *Touhy* regulations should not apply where the Government is a party to the litigation.” *U.S. ex rel. Roby v. Boeing Co.*, 189 F.R.D. 512, 518 (W.D. Ohio 1999) (*Touhy* did not apply to DoD requests because “the Government is a party to the litigation.”); *Alexander*, 186 F.R.D. at 71 (same).

Party Discovery: The Court should put a stop to the government’s behavior by including the Agencies in party discovery. That is precisely what the court in *AT&T* recognized when it ordered party discovery from 40 agencies. *U.S. v. Am. Tel. & Tel. Co.*, 461 F. Supp. 1314, 1331

¹ CPB conditioned withdrawing DoD’s objection on Walmart’s withdrawing its waiver objection.

(D.D.C. 1978) (“When dealing with the government, effective sanctions are not available for noncompliance with requests under Rule 45.”).

The Court’s September 25 Order rested on its findings that the Agencies were not “so closely aligned with the DOJ as to be part of the prosecuting team or having contributed significantly to this investigation” and that Walmart could “seek discovery through subpoenas.” D.I. 151 at 55:6–9, 56:1–3 (Ex. L). Neither has turned out to be true. Subsequent to the hearing, the government produced discovery responses showing that DoD and HHS investigators *attended interviews of Walmart witnesses*. See Exhibit to 12/16/24 U.S. Resps. (Ex. V). While Walmart is blind to how else these agencies may have participated in the investigation, interviewing a company’s former employees in an attempt to advance an enforcement action is significant by any measure. After the hearing, Walmart also learned that throughout the Walmart investigation DoD and HHS had been working with the government on the False Claims Act portion of that investigation, which the government ultimately elected not to pursue. Thus, when the government told the Court that DoD and HHS had not “contributed significantly to the investigation or prosecution of the case,” it was evidently parsing the word “investigation” to exclude claims it investigated but abandoned. Similarly, after claiming the Agencies were independent of the DOJ’s efforts generally, the CPB now represents all of them in a joint effort to subvert the subpoenas.

What it all amounts to is the government playing games to avoid its discovery obligations. And the problem seems only to be getting worse. Ascribing incredible meanings to simple words like “investigation” and ignoring subpoenas because of frivolous objections now will likely turn into fighting the admissibility of government documents (FRE 801(d)(2)) and refusing to produce government witnesses at trial (FRCP 45(c)(1)) later. And because the Agencies’ materials are unquestionably within the government’s “possession, custody, or control” it is well within the Court’s discretion under Rule 34 to do so. See Fed. R. Civ. P. 34(a)(1).

Walmart respectfully asks the Court to enter the attached Order.

Respectfully,

/s/ Kelly E. Farnan

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Attachments

cc: All Counsel of Record (w/e) (By E-Mail)

CERTIFICATE OF SERVICE

I hereby certify that on February 14, 2025, true and correct copies of the foregoing document were caused to be served on the following counsel of record as indicated:

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